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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,863	11/03/2003	Balaram Ghosh	C261 1030.1	9355

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,863

Applicant(s)

GHOSH ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 21, 2006 has been entered.

Acknowledgment is made of Applicant's cancellation of Claims 3 and 9.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-8 and 10-13 are under examination.

Response to Arguments

Claims 1, 2, 4-8, 10, 12 and 13 is/are remain rejected under 35 U.S.C. 102(b) as being anticipated by Aoyama et al. (N). Applicant's arguments have been fully considered. However, the rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant claims a method of preventing and/or treating asthma in animals including humans using natural compound luteolin, said method comprising administering a composition consisting essentially of a therapeutically effective dose of the luteolin to the animal, wherein the luteolin is administered orally, and wherein the

luteolin is administered in an amount in a range of 0.1 to 10mg/kg of body weight of the animal.

Applicant argues, "Aoyama appears to teach the extraction and use of a crude product, or alternatively, the extraction and purification of apigenin, since it has the highest activity." Applicant's main argument is directed to the idea that the amendment to independent Claim 1 overcomes the teachings of Aoyama because Aoyama does not disclose what a therapeutic amount of any single compound in the disclosed extract may be, let alone what a therapeutic effective amount of luteolin might be (for use in the disclosed prior art method of treatment). Each of Applicant's arguments have been fully considered but found unpersuasive because Aoyama teaches a method of preventing and/or treating asthma in animals comprising orally administering an effective amount of an alcoholic extract obtained from the *Perilla* seed, which comprises luteolin or a concentrated extract therefrom comprising luteolin alone; and, also a method of preventing and/or treating asthma in animals comprising the oral administration of a composition comprising a therapeutically effective dose of luteolin alone to an animal. While Aoyama does indicate that apigenin has the highest activity, Applicant should not look at the teachings of Aoyama in a vacuum because Aoyama clearly teaches that luteolin, as well as apigenin and other disclosed compounds, is useful and capable of effectively treating and/or preventing asthma by oral administration of therapeutic amounts thereof. For example, Aoyama teaches each of the disclosed histamine isolation inhibitor compounds, as well as the crude product extract from which they are obtained, as a histamine release inhibitor, which is extremely good in action of inhibiting

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the release of histamine or the development of asthmatic features comprising Early Airway Response (EAR). In [0027], Aoyama clearly teaches administering 0.5-3000 mg/day of the referenced histamine isolation inhibitor or 0.3 to 15% weight percent or 0.01-10 weight percent to a patient in need thereof of treatment. Hence, Aoyama expressly teaches each of apigenin, chrysoeriol, luteolin and rosmarinic acid as histamine release inhibitors, as well as *Perilla* seed alcohol extracts containing the aforementioned compounds and an EtOAc fraction of *Perilla* seed extract as inhibitors of histamine release, which are useful in the prevention and/or treatment of allergic disease conditions, such as asthma. Furthermore, in [0010], Aoyama expressly teaches that luteolin can be extracted from perilla seed and used in the making of both drugs and food products to provide an oral delivery vehicle for use in the disclosed method of treatment, such as the food product comprising luteolin alone discussed at [0058].

Contrary to Applicant's argument that Aoyama does not teach treatment of asthma comprising the administration of a composition consisting essentially of luteolin, Aoyama expressly teaches that the bioactive compounds contained in the disclosed *Perilla* seed extract can be concentrated, condensed or isolated from the plant seed extract, in [0020] through [0023]. Aoyama also teaches that while the referenced extracts are considered as histamine release inhibitors, refining of the active principle compounds contained therein the extracts can be isolated and that fractions with the highest activity can be collected and used as histamine release inhibitors for treatments or prophylaxis of allergic diseases, such as asthma. In [0031], Aoyama teaches a

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method of isolating luteolin from *Perilla* seed extract. Hence, the method of treatment taught by Aoyama is not only directed to the administration of effective amounts of *Perilla* seed extract or fractions thereof comprising luteolin but also the administration of effective amounts of each of the individual compounds contained therein (including luteolin) to provide the claimed beneficial functional effect for the claim-designated disease condition. See [0010], wherein Aoyama expressly teaches that each of apigenin, chrysoeriol, luteolin and rosmarinic acid may be efficiently extracted from the seed extract and used in the making of therapeutic preparations for oral administration. Applicant is also directed to [0006] wherein Aoyama clearly teaches that that the disclosed compositions useful for treating and/or preventing asthma may consist essentially of one or more of the disclosed histamine release inhibitors, such as luteolin. Again, the Office points to [0027] wherein Aoyama clearly teaches the effective dose range amounts of the histamine release inhibitors for the making of oral pharmaceuticals to be administered to patients in the treatment or allergic diseases, such as asthma: "0.5-3000 mg is usually suitable for in an adult, although a dose may change with the age or a medication method, condition of disease, and a patient etc. at 0.5-500 mg and a child as an active principle per day ...". Furthermore, in [0029], Aoyama expressly teaches that the referenced histamine isolation inhibitors can substantially reduce an allergic response, such as cellular degranulation (an asthmatic feature of Late Airway Response). For instance, Aoyama teaches, "Therefore, the histamine isolation inhibitor of this invention can treat or prevent effectively the pollinosis which is many symptoms of I-beam allergy, asthma, dry grass heat, rhinitis, urticaria, a

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drug allergy, etc. Moreover, it becomes possible to prevent allergy in an every day life and to improve a body easily with the allergy prevention external preparations and allergy prevention food containing the histamine isolation inhibitor of this invention." Moreover, Aoyama clearly teaches that the administration of the referenced compounds, including luteolin, and extracts or fractions thereof comprising luteolin inhibit the release of histamine, which is a symptomatic developmental feature of EAR; and, as set forth immediately above, Aoyama clearly teaches that the referenced histamine isolation inhibitors substantially reduce cellular degranulation, which is a symptomatic developmental feature of LAR. In [0002] - [0003], Aoyama also clearly describes the progressive biomechanisms that lead to the development of allergic responses in allergic disease, such as asthma, and expressly teaches that by controlling or suppressing the release of histamine, one may also prevent symptoms of LAR, e.g., the production of mast cells and IgE. Since, the administration of effective amounts of the compositions taught by Aoyama inhibits the release of histamine, the method of treatment taught by Aoyama would indeed prevent the development of asthmatic features comprising both EAR and LAR.

Finally, while Applicant may continue to argue that Aoyama does not expressly teach that the referenced method of treatment prevents development of asthmatic features comprising Early Airway Response (EAR) and Late Airway Response, or any of the claimed functional effects of increasing IFN-gamma to a normal level and decreasing each of IL-5, IL-4 or IgE to a normal level, or wherein luteolin inhibits airway constriction or airway hyperactivity, *per se*. However, the method of treatment taught by

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Aoyama comprises the oral administration of the same ingredient in the same amounts to provide the same beneficial functional effect for the prevention of asthma in patients in need thereof of such treatment. Therefore, the claimed functional effects for the prevention of the development of asthmatic features comprising Early Airway Response (EAR) and Late Airway Response, and the claimed functional effects of increasing IFN-gamma to a normal level and decreasing each of IL-5, IL-4 or IgE to a normal level and the inhibition of airway constriction and airway hyperactivity are inherent to the method of treatment taught by Aoyama.

The reference anticipates the claimed subject matter.

Claim 1, as amended, and Claims 2, 4-8 and 10-13 is/are remain rejected under 35 U.S.C. 102(b) as being anticipated by Wang (U). Applicant's arguments have been fully considered. However, the rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant's claimed invention was set forth above.

Applicant argues the teachings of Wang is directed to the use of luteolin for the effective treatment of bronchitis; and, therefore, the rejection made in the previous Office action based on inherency fails to provide an anticipatory teachings of the claimed invention because, "The treatment of asthma does not necessarily flow from the administration of luteolin to bronchitis patients", since, "Bronchitis and asthma are separate indications, and only a small percentage of people with bronchitis develop asthma." Therefore, Applicant concludes, "The treatment of asthma does not

necessarily flow from the administration of luteolin to bronchitis patients.” However, without a clear and substantial teaching supporting Applicant’s conjecture that only a small percentage of people with bronchitis develop asthma, Applicant’s arguments are not persuasive. Nonetheless, Applicant has clearly provided a nexus between the disease conditions of bronchitis and asthma, and the treatment of patients suffering from asthma associated with bronchitis and patients suffering bronchitis who are susceptible to the development of asthma since it is well known in the art of medicine that asthma is a symptom of bronchitis, as clearly indicated by the teachings of Wang and as readily admitted by Applicant in the “Remarks” filed on July 26, 2005. Moreover, Wang teaches a method of orally administering an effective amount of luteolin obtained from plant sources (120 mg/day p.o.) for 10 days to patients with bronchitis. On page 148, Column 2, under “*Clinical Studies*”, Wang teaches, “The major symptoms of chronic bronchitis, including cough, asthma, sputum and wheezing, were effectively alleviated with luteolin treatment (Table VI). No liver, cardiac or renal toxicity was reported.” Thus, while Applicant may argue that Wang’s method of treating patients with asthma associated with bronchitis comprising the administration of effective dose amounts of a composition consisting essentially of luteolin does not necessarily lead one to the conclusion that all asthma patients including those not suffering from bronchitis would be effectively treated by luteolin, the Office notes that Wang clearly teaches the instantly claimed invention because Wang teaches a method of treating asthma comprising the oral administration of therapeutically effective amounts of luteolin (in the same amounts as instantly claimed by Applicant) to a patient population

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suffering asthma with associated bronchitis, wherein the referenced method was taught as effectively alleviating symptoms of asthma; and, thereby, Wang also teaches the instantly claimed method for the prevention of asthma because Wang teaches that the oral administration of therapeutically effective amounts of luteolin (which are the same amounts as instantly claimed by Applicant) to patient population susceptible to the development of asthma, effectively eliminates symptoms of asthma. See Table IV, on page 148, wherein Wang indicates a rate of 93.3% complete remission of asthma symptoms in bronchitis patients treated with luteolin.

While Wang does not expressly teach that the referenced method of treatment prevents development of asthmatic features comprising Early Airway Response (EAR) and Late Airway Response, or any of the claimed functional effects of increasing IFN-gamma to a normal level and decreasing each of IL-5, IL-4 or IgE to a normal level, or wherein luteolin inhibits airway constriction or airway hyperactivity, *per se*, the method of treatment taught by Wang comprises the oral administration of the same ingredient in the same amounts to provide the same beneficial functional effect for at least the treatment of asthma in patients suffering bronchitis and in need thereof of such treatment and at least the prevention of asthma in patients in need thereof of such treatment. Therefore, the claimed functional effects for the prevention of the development of asthmatic features comprising Early Airway Response (EAR) and Late Airway Response, and the claimed functional effects of increasing IFN-gamma to a normal level and decreasing each of IL-5, IL-4 or IgE to a normal level and the inhibition of airway constriction and airway hyperactivity are inherent to the methods of treatment

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and/or prevention taught by Wang, especially in view of Wang teaching that luteolin treatment provided a rate of 93.3% complete remission of asthma symptoms in bronchitis patients treated with luteolin.

The reference anticipates the claimed subject matter.

Claim 1, as amended, and Claims 2, 4-8 and 10-13 is/are/ rejected under 35 U.S.C. 102(b) as being anticipated by Murai et al. (A*).

Applicant's claimed invention was set forth above.

Murai teaches a method of preventing asthma in animals comprising the oral administration of a therapeutically effective amount of luteolin, wherein the luteolin is administered in an amount range of 0.5 to 5000 mg to adults and in an amount range of 0.5 to 3000 mg to children for a least a time period in a range of 5 to 10 days. See Column 1, line 16 to Column 2, line 52; Column 5, lines 11-15; Column 10, lines 47-67; and, patent Claims 8, 12, 16, 17 and 18.

Murai does not expressly that teach the referenced method prevents development of asthmatic features comprising Early Airway Response (EAR) and Late Airway Response, or any of the claimed functional effects of increasing IFN-gamma to a normal level and decreasing each of IL-5, IL-4 or IgE to a normal level, or wherein luteolin inhibits airway constriction or airway hyperactivity, *per se*. However, the method of prevention taught by Murai comprises the oral administration of the same ingredient in the same amounts to provide the same beneficial functional effect for at least the prevention of asthma. Therefore, the claimed functional effects for the prevention of the

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development of asthmatic features comprising Early Airway Response (EAR) and Late Airway Response, and the claimed functional effects of increasing IFN-gamma to a normal level and decreasing each of IL-5, IL-4 or IgE to a normal level and the inhibition of airway constriction and airway hyperactivity are inherent to the method for the prevention of asthma taught by Murai.

The reference anticipates the claimed subject matter.

Claim 1, as amended, and Claims 2, 4-8 and 10, 12 and 13 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Kotani et al. (N).

Applicant's claimed invention was set forth above.

Kotani teaches a method of preventing asthma in an animal comprising the oral administration of a therapeutically effective amount of luteolin to a patient, wherein the therapeutically amount of luteolin is in a range of 0.025-3 mg/kg of the body weight of the patient. See [0016] and [0048]. Kotani teaches that the oral administration of luteolin has the beneficial functional effect for inhibiting Th2 cytokine, IL-4, IL-5 and IgE production, and immediate-type allergy reaction at [0059].

Kotani does not expressly that teach the referenced method prevents development of asthmatic features comprising Early Airway Response (EAR) and Late Airway Response, or the claimed functional effects of increasing IFN-gamma to a normal level or wherein luteolin inhibits airway constriction or airway hyperactivity, *per se*. However, the method of prevention taught by Kotani comprises the oral administration of the same ingredient in the same amounts to provide the same

beneficial functional effect for at least the prevention of asthma. Therefore, the aforementioned claim-designated functional effects are inherent to the prophylactic method of treatment taught by Kotani.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murai et al. (A*, US 6,217,875) in view of Tanaka et al. (U) and Nagai et al. (W).

The teachings of Murai are set forth above. Murai does not expressly teach a method of treating asthma in animals comprising the administration of a therapeutically effective dose amount of luteolin to animals *per se*. However, it would have been obvious to one of ordinary skill in the art to adapt the method of preventing asthma in animals taught by Murai to a method of treating asthma in a patient because at the time the invention was made Tanaka suggested the use of luteolin as an anti-allergic drug for the treatment of asthma in patients because flavonoids, such as luteolin, inhibit activity of hexosaminidase release from mast cells, inhibit the release of histamine from mast cells or basophils and suppress cysteinyl leukotriene synthesis through an inhibition of phospholipase A2 (PLA2) and/ or 5-lipoxygenase, on page 59, second paragraph to page 60, first paragraph; and, like Tanaka, Nagai suggested the use of luteolin for the treatment of asthma. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of

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success to adapt the method of preventing asthma taught by Murai to the instantly claimed method of treating asthma in a patient because Murai taught luteolin as an inhibitor of 5-lipoxygenase, which metabolizes arachidonic acid into 5-hydroxy-6,8,10,14-eicosatetraenoic acid (5-HETE), and induces the formation of leukotriene (LT) which is associated with allergic diseases, inflammatory disease and asthma, in Column 1, lines 33-43; and, Tanaka taught, "The inhibitory effect of several flavonoids (such as the luteolin used in the method of treatment taught by Murai) on the PLA2 and 5LO was recently reviewed [citation omitted]. PLA2 releases arachidonic acid from membrane phospholipids and is metabolized by the 5LO pathway, leading to biosynthesis of cysteinyl leukotrienes, which are important mediators for pathogenesis of asthma", on page 60, lines 6-11; moreover, on page 60, second Column, first paragraph, Tanaka teaches that luteolin inhibited the production of both IL-4 and IL-5; and, Nagai demonstrated the effect of luteolin to inhibit both histamine release from mast cells and cytokine production, the inhibition of immediate phase reaction and late phase reaction in relation to allergic reactions with IgE-dependent mast cells, which are mediators of asthma pathogenesis.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1, 2, 4-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kotani et al. (O) in view of Tanaka et al. (U) and Nagai et al. (W).

The teachings of Kotani are set forth above. Kotani does not expressly teach a method of treating asthma in animals comprising the administration of a therapeutically effective dose amount of luteolin to animals *per se*. However, it would have been obvious to one of ordinary skill in the art to adapt the method of preventing asthma in animals taught by Kotani to a method of treating asthma in a patient because at the time the invention was made Tanaka suggested the use of luteolin as an anti-allergic drug for the treatment of asthma in patients because flavonoids, such as luteolin, inhibit activity of hexosaminidase release from mast cells, inhibit the release of histamine from mast cells or basophils and suppress cysteinyl leukotriene synthesis through an inhibition of phospholipase A2 (PLA2) and/ or 5-lipoxygenase, on page 59, second paragraph to page 60, first paragraph; and, like Tanaka, Nagai suggested the use of luteolin for the treatment of asthma. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to adapt the method of preventing asthma taught by Kotani to the instantly claimed method of treating asthma in a patient because Kotani taught luteolin as a controller or modifier of chronic allergic inflammatory disease conditions, which could be taken over a long period of time to suppress allergic reactions mediated by IgE production control based on manifestation of control of IL-4 and IL-5; and, Tanaka taught, "The inhibitory effect of several flavonoids (such as the luteolin used in the method of treatment taught by Kotani) on the PLA2 and 5LO was recently reviewed

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[citation omitted]. PLA2 releases arachidonic acid from membrane phospholipids and is metabolized by the 5LO pathway, leading to biosynthesis of cysteinyl leukotrienes, which are important mediators for pathogenesis of asthma", on page 60, lines 6-11; moreover, on page 60, second Column, first paragraph, Tanaka teaches that luteolin inhibited the production of both IL-4 and IL-5; and, and, Nagai demonstrated the effect of luteolin to inhibit both histamine release from mast cells and cytokine production, the inhibition of immediate phase reaction and late phase reaction in relation to allergic reactions with IgE-dependent mast cells, which are mediators of asthma pathogenesis

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
April 15, 2006